

## **REMARKS**

Upon entry of this paper, no claims have been amended, no claims have been cancelled, and claim 53 has been added as a new claim. Thus, claims 1-27 and 44-53 are presently pending in this application. No new matter has been added.

Applicants gratefully thank the examiner for the indication of allowability of claims 45-49. In addition, applicants respectfully submit that all claims pending in the present application are allowable as described herein.

Applicants further thank the examiner for the indication of allowability of claim 3 if re-written in independent form to include all the limitations of the base claim and any intervening claims. Applicants believe all claims to be allowable, but have added new claim 53, which is equivalent to claim 3 re-written in independent form including the limitations of claim 1 from which it depends. Because the examiner has indicated the allowability of claim 3 if re-written in the form of new claim 53, Applicants submit that there no new issues are being presented with the addition of claim 53, and that no new search is required.

### **Claim Rejections under 35 U.S.C. §102**

Claims 1, 2, 4-27, 44, and 50-52 were rejected under 35 U.S.C. §102(e) as being anticipated by US Patent Number 5,269,755 to Bodicky, et al. (Bodicky '755). This anticipatory rejection is respectfully traversed in view of the following remarks.

Bodicky '755 is generally directed to a Foley catheter having an inflatable balloon portion that inflates in the bladder of a patient and prevents the catheter from being removed until the balloon is deflated. The Foley catheter further includes an outer sheath made of a porous polymer material such as expanded polytetrafluoroethylene (ePTFE) placed proximal to the inflatable balloon portion. The sheath has a porosity to allow anti-

microbial or anti-bacterial medicament or other medicaments or liquids to pass through the sheath. A medicament lumen is provided passing through the elongated tube of the catheter from the catheter's proximal or out of patient end to openings along the catheter tube wall. Medicament is passed from the proximal end of the catheter through the medicament lumen and expelled through the openings into the area between the sheath and the catheter's main tube. There, the medicament or other liquid passes through the sheath into contact with the patient's body lumen.

Applicants respectfully submit that Bodicky '755 fails to anticipate the present claimed invention. Bodicky '755 does not disclose a member with a, “. . . wall being formed of a microstructure of nodes interconnected by fibrils, *the member being deployable from a first, reduced diameter configuration to a second, increased diameter configuration.*” See claim 1.

The Office Action refers to column 5, lines 23-27, as teaching the above claim language. This section of Bodicky '755 is repeated below:

“Pores E are formed between the interconnected nodes C and fibrils D. The size of pores E is a function of whether fibrils D are stretched, relaxed or compressed between nodes C which is in turn a function of whether ePTFE sheath 40 is stretched or compressed.”

The indication that the sheath 40 can be stretched or compressed is not a disclosure that the sheath 40 is a radially expandable device deployable from a first, reduced diameter to a second, increased diameter configuration. Such stretching and compression, as described in Bodicky '755, merely indicates a longitudinal direction of movement, rather than a radial direction.

In further support that the sheath 40 is not a radially expandable device, the figures of Bodicky '755 show the Foley catheter with the balloon portion on the end of

the catheter inflated. However, there is no indication in the figures of the sheath 40 experiencing any change in radial dimension.

As such, Applicants respectfully submit that Bodicky '755 fails to anticipate the pending claims. Applicants request reconsideration and withdrawal of this rejection.

**Claim Rejections under 35 U.S.C. §103**

Claims 21-23 and 51-52 were rejected under 35 U.S.C. §103 as allegedly being unpatentable over Bodicky '755. This rejection is respectfully traversed in view of the following comments.

In view of the above remarks, Bodicky '755 fails to teach or suggest all elements of the pending claim 1, from which claims 21-23 depend. Claims 51-52 likewise depend from a claim (claim 50) that includes the same element in claim 1 of having a member deployable from a first, reduced diameter configuration to a second, increased diameter configuration. As such, Bodicky '755 fails to teach or suggest all elements of claim 50.

Applicants respectfully submit that unless a *prima facie* case of unpatentability with respect to known facts is established, applicants are not obliged to proffer any evidence of nonobviousness. To establish a *prima facie* case there must be some suggestion or motivation, either in the prior art or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine multiple reference teachings. There must then be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claimed limitations.

Again, Applicants respectfully submit that the sheath 40 is not a radially expandable device as evidenced by the figures of Bodicky '755. The noted figures show the Foley catheter with the balloon portion on the end of the catheter inflated. However,

there is no indication in the figures of the sheath 40 experiencing any change in radial dimension.

In fact, Bodicky '755 teaches away from the assertion that the sheath is a radially expandable member as would be required to anticipate or make obvious the pending claims. There is no indication whatsoever that the sheath 40 in Bodicky '755 is in any way radially expandable. Contrarily, Bodicky '755 implicitly discloses that the sheath 40 is not a radially expandable balloon, because Bodicky '755 uses the "balloon" terminology to describe another portion of the Foley catheter, and specifically chose to alter the terminology and use the different term of a "sheath" to describe the ePTFE portion of the catheter, thus teaching away from the assertion that the ePTFE section be formed of a radially expandable member.

Furthermore, various dictionary definitions of "sheath" indicate a case for a knife, or any of various similar coverings, or an investing cover or case of a plant or animal body or body part. There is no interpretation of "sheath", either in Bodicky '755 or in the conventional English language, that would indicate the sheath 40 having the ability to deploy from a first, reduced diameter to a second, increased diameter configuration.

Applicants, therefore, respectfully submit that the pending claims are non-obvious with respect to Bodicky '755. Reconsideration and withdrawal of this rejection are accordingly requested.

**Prior Rejections Are Withdrawn**

The Office Action indicates that Applicants' arguments with respect to the claims are moot in view of the new grounds of rejection. There is no reference to, or maintenance of, the prior grounds of rejection. Under MPEP §707.07(e) and *Paperless Accounting, Inc. v. Bay Area Rapid Transit System*, 804 F.2d 659, 231 USPQ 649, a

requirements or rejection in a prior Office Action is withdrawn if the examiner does not repeat or refer to that requirement or rejection.

Accordingly, Applicants consider all rejections and objections to be either addressed or withdrawn upon filing of this Response. As such, Applicants respectfully submit that all pending claims are allowable, and action to that end is requested.

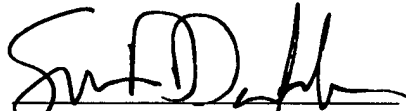
### CONCLUSION

In view of the foregoing, it is respectfully submitted that this application is now in condition for allowance. Applicants courteously solicit allowance of the claims in the form of a Notice of Allowance. Should there be any outstanding issues of patentability following the entry of this response, a telephone interview is respectfully requested to resolve such issues.

Please charge any shortage or credit any overpayment of fees to our Deposit Account No. 12-0080. In the event that a petition for an extension of time is required to be submitted herewith, and the requisite petition does not accompany this response, the undersigned hereby petitions under 37 C.F.R. §1.136(a) for an extension of time for as many months as are required to render this submission timely. Any fee due is authorized to be charged to the aforementioned Deposit Account. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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